DEC 1 7 2001

510(k) Summary

K013352

page 1 of 2

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Marcia J. Arentz** Senior Regulatory Associate Phone: (219) 371-4944 FAX: (219) 371-4987
Trade Name:	**Summit™ Cemented Hip Prosthesis**
Common Name:	Total Hip Joint Replacement Prosthesis
Classification:	**Class II** Device per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis
Device Product Code:	Code: **87JDI** Prosthesis Hip Semi-constrained, Metal/Polymer, cemented No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.
Substantially Equivalent Device:	Endurance Total Hip System **K942370** P.F.C. Hip System **K900638** Vision AML Hip Prosthesis **K953694**
Device Descriptions:	The Summit™ Cemented Hip Prosthesis is a flanged, collared, tapered Cobalt-Chromium femoral stem with a smooth surface finish. There are 7 proportional body sizes with two offset options. Distal and proximal PMMA centralizers help assure the stem is centered in the femoral canal.

510(k) Summary (continued)

Intended use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for use:

Total hip replacement is indicated in the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic facture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthro-plasty, or total hip replacement.
5. Certain cases of ankylosis.

Substantial equivalence:

The Summit Cemented Hip Prosthesis has the same intended use and basic design as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Incorporated
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K013352
Trade Name: Summit Cemented Hip Prosthesis
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: October 3, 2001
Received: October 9, 2001

Dear Ms. Arentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013352

Device Name: Summit™ Cemented Hip Prosthesis

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Cemented Components:

Femoral stem and acetabular cup total hip components labeled "For cemented use only" are indicated only for use with bone cement.

This device is intended for single use.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013352

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)